UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX
75 Hawthorne Street
San Francisco, CA 94105
http://www.epa.gov/region9/waste/enforcement/index.html

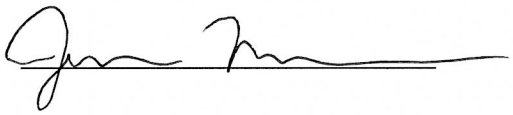
Purpose:	RCRA Compliance Evaluation Inspection
Facility Name:	USC Norris Cancer Hospital
Facility Location:	1441 Eastlake Ave. Los Angeles, CA 90089
Mailing Address:	Keck Medical Center of USC 1500 San Pablo Street Los Angeles, CA 90033
EPA ID Number:	CAL 000 309 829 CAL 000 396 462
Date/Time of Inspection:	September 16, 2014 @ 10:00 a.m.
EPA Representative:	Jennifer MacArthur Enforcement Officer (415) 972-3994 macarthur.jennifer@epa.gov John Brock Enforcement Officer (415) 972-3999 brock.john@epa.gov
Facility Representative:	Karen Chapman Executive Administrator (323) 442-8862 Karen.chapman@health.usc.edu Robert Vance Emergency Management & Business Continuity Tarek Salaway Chief Operating Officer

Marianne Silva
Quality, Regulatory & Compliance Manager

John Glover
General Manager

Report Date: November 19, 2014

Report Prepared by: Jennifer MacArthur



A. Introduction

On September 16, 2014 representative of the U.S. Environmental Protection Agency (EPA) conducted an unannounced hazardous waste management compliance evaluation inspection (CEI) of the USC Norris Cancer Hospital (USC) which is part of the Kleck School of Medicine. The purpose of the inspection was to determine USC's compliance with applicable federal environmental statutes and regulations, and in particular, the Resource Conservation and Recovery Act (RCRA), as amended, the regulations provided in the Code of Federal Regulations (CFR), Chapter 40, Parts 261-265, 268, 273, and 279, and the California Code Regulations (CCR), Title 22, Division 4.5 and the California Health and Safety Code, Division 20.

B. Facility Background

Facility Web-Site	http://uscnorriscancer.usc.edu/
Site History	USC Norris Cancer Hospital has operated in its current location since the late 1980s.
Number of Employees	Approximately 478
Hours of Operation	24/7/365
Facility Operations	USC Norris Cancer Hospital is a center for cancer research, treatment, prevention and education. The facility includes a 24/7 hospital with 60 beds, an inpatient and outpatient pharmacy, and they serve roughly 6000 new patients per year.
RCRA and Non-RCRA Hazardous Wastes Streams	EPA Waste Codes: D001, D002, D009, D011, F003, U010, U058, universal waste lamps and batteries, used oil
Generator Status	small quantity generator (SQG) of hazardous waste
Compliance History	No previous inspections are documented in RCRAInfo
SIC/NAICS Codes	NAICS Code: 622310 – Specialty Hospitals

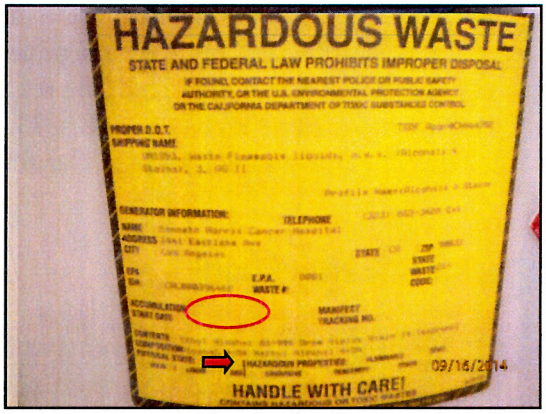
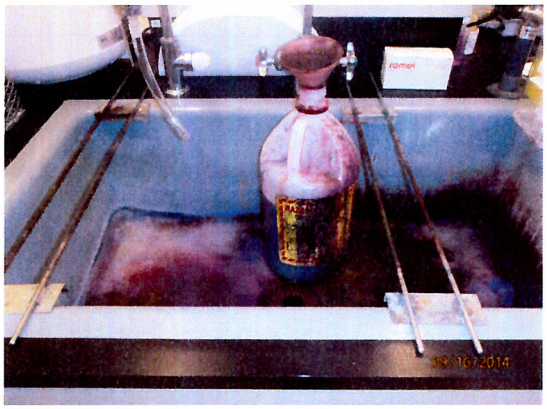
C. On-Site Inspection

The on-site inspection portion of the CEI started at the Main Clinical Laboratory and ended at the CTU Clinical Laboratory.

1. Facility and Satellite Accumulation Areas

The inspectors observed 2 hazardous waste satellite accumulation areas ("SAAs") in the Main Clinical Laboratory, a SAA in the outpatient pharmacy and a SAA in the inpatient pharmacy. Waste was being accumulated in these areas in poly containers ranging from 2-gallons in size to 20-gallons.

The following table summarizes the observations made during the on-site inspection portion of the CEI for all areas except the facility's waste accumulation area (i.e., less than 90/180 day storage area).

Observation	Photograph
1. *The inspectors observed a SAA container of ethyl alcohol (D001) in the main clinical laboratory area which was not marked with an accumulation start date or the hazardous properties of the waste*	 Photo No. 8
2. *The inspectors observed an approximately 2-gallon SAA container of iodine stain (D001) waste in a sink area. The container was open and information on label was unreadable*	 Photo No. 11
3. *The inspectors observed a black bin container for bulk or pourable RCRA waste in vials in the outpatient pharmacy. A list attached to the container identified the exact contents. Further review of the list revealed that USC routinely generates small amounts of acutely hazardous arsenic trioxide (P012) which isn't listed on USC's hazardous waste manifests*	 Photo No. 14

2. Waste Accumulation Area (less than 90/180 day hazardous waste accumulation area)

USC did not have a true 180-day hazardous waste accumulation area at the time of the inspection. USC has a contract with Stericycle which removes hazardous waste containers directly from the hospital's SAAs. USC did have universal waste storage areas. Universal waste lamps were stored near the maintenance department and universal waste batteries were stored in the environmental department offices.

The following table summarizes the observations made during the walk-through portion of the facility's waste accumulation areas.

Observation	Photograph
1. *The inspectors observed used universal waste lamps in cardboard boxes which were not fully closed and were not labelled as "universal waste – lamps"*	 Photo No. 12

D. Record Review

Record	Year(s)	Observation(s)
Manifests	2012 - current	Reviewed
Land Disposal Restriction ("LDR") Notifications	2012 - current	Reviewed
Contingency Plan/Emergency Contact Info	Current	Reviewed
Training Records and Documentation	Current	Reviewed

During the inspection the inspectors discovered that USC applied for and was issued a second/new California-only ID number earlier this year as part of reorganizational activities. USC's new number is CAL 000 396 462 and they have been manifesting hazardous waste offsite under this new number since July 2014. The inspectors informed USC that they need to apply

for a Federal EPA ID number and that a California-only ID number is only for generators that exclusively generate non-RCRA hazardous wastes.

During the inspection the inspectors took copies of the Chemical Waste Disposal Record sheet attached to the black bins in the 2 pharmacies (Attachment 2). The sheet lists the chemical name, concentration, and residual milligrams/volume of every container that goes into the black bin. The chemicals listed on the sheets were compared to recent hazardous waste manifests years and it was noted that not all of the wastes on the bin were noted on the manifest. One of these wastes, arsenic trioxide, is an acutely-hazardous waste (P012). The lab packs on USC's manifests only list U010 and U058waste.

Areas of Concern

1. According to information gathered during the inspection, USC relies on their contractor, Stericycle Specialty Waste Solutions Inc., to make waste determinations, label and date hazardous waste, conduct inspections of hazardous waste storage areas, etc. At the time of the inspection USC representatives were unsure of whether or not they generated any acutely hazardous (P-listed) waste or how generating such waste could/would affect their generator status. USC should be familiar with all of the waste streams they generate and the associated requirements. If USC generates more than 1 kg of acutely hazardous waste in a month then they would be considered a large quantity generator and would be subject to additional regulatory requirements.

2. During the inspection USC representatives mentioned that they were in the initial planning stages of implementing a take-back program for their pharmacy. EPA encourages USC to thoroughly familiarize themselves with local, state and federal regulations regarding take-back and reverse distribution of unused pharmaceuticals to ensure USC's compliance with applicable regulations.

POTENTIAL VIOLATIONS
of
California Title 22 and RCRA 40 CFR
Hazardous Waste Management Regulations

NO.	STATUTE OR REGULATION	REGULATION SUMMARY	FINDING(s)
1	*40 CFR § 262.34(c); 265.173 [CCR 66262.34(e); 66265.173]]*	*A generator may accumulate as much as 55 gallons of hazardous waste at or near the point of generation as long as certain requirements are met. These requirements include marking the container with the words "hazardous waste" or with other words that identify the contents of the container. A container holding hazardous waste must be closed during storage except when it is necessary to add or remove waste*	*The inspectors observed an approximately 2-gallon SAA container of iodine stain (D001) waste in a sink area. The container was open and information on label was unreadable*
2	*40 CFR §262.20; 268.42(c) [CCR 66262.20]*	*A generator who transports hazardous waste for offsite treatment, storage or disposal must prepare a Manifest on EPA Form 8700-22 according to instructions. These instructions include: entering up to six federal and state waste codes to describe each waste stream identified in Item 9b. State waste codes that are not redundant with federal codes must be entered here, in addition to the federal waste codes which are most representative of the properties of the waste.* *Lab packs are eligible for land disposal provided they meet certain conditions.*	*The 2013 and 2014 manifests reviewed during the inspection consistently listed only waste codes U010 and U058 for all lab pack chemotherapy prescriptions manifested offsite. However, the list of chemicals attached to USC's bulk chemotherapy waste container listed chemicals with additional waste codes (e.g. Melphalan – U150 and arsenic trioxide –P012). These additional waste codes should also be noted on the manifests and USC should ensure they are in compliance with all the lab pack requirements under 265.316 and 268.42(c)*

NO.	STATUTE OR REGULATION	REGULATION SUMMARY	FINDING(s)
3	*40 CFR § 273.13(d); 273.14(e) [CCR 66273.33(b); 66273.34(c)]*	*A small quantity handler of universal waste must manage lamps in a way that prevents releases of any universal waste or any universal waste component to the environment. A small quantity handler of universal waste must label or mark containers as "universal waste – lamps" or "waste lamps" or "used lamps"*	*Universal waste lamps were being stored in open and unlabeled cardboard boxes*
4	*40 CFR § 262.12(a) [CCR 66262.12(a)]*	*A generator must not treat, store, dispose of, transport, or offer for transportation , hazardous waste without having received an EPA identification number*	*USC has been manifesting hazardous waste using a California-only ID number which is only for generators that exclusively generate non-RCRA (California-only) hazardous wastes. USC needs to apply for a Federal EPA ID number*

POTENTIAL VIOLATIONS
of
California Title 22
Hazardous Waste Management Regulations

NO.	STATUTE OR REGULATION	REGULATION SUMMARY	FINDING(s)
1	*22 CCR 66262.34(e)(1)*	*A generator may accumulate as much as 55 gallons of hazardous waste at or near the point of generation without a permit as long as certain conditions are met; these conditions include clearly marking the initial date of accumulation and the hazardous properties of the waste on the container*	*The inspectors observed a SAA container of ethyl alcohol in the main clinical laboratory area which was not marked with an accumulation start date or the hazardous properties of the waste*

List of Attachments

1. Photograph Log & Inspection Photos
2. USC Norris Cancer Hospital Chemical Waste Disposal Records 8-17-14 and 9-4-14

Photograph Log for EPA's September 16, 2014
USC Norris Cancer Hospital RCRA Inspection

All photographs on this log were taken with an Olympus Tough TG-310 by John Brock, Enforcement Division, EPA Region IX. Please note that each photograph number listed below begins with "P91600" and the log starts with photograph number 08.

08. SAA container of ethyl alcohol in main clinical laboratory area. The container label was not marked with an accumulation start date or the hazardous properties

09. Close-up of hazardous waste label on SAA container in photo #8

10. Accidental photograph taken

11. Small poly container/bottle in sink area containing iodine stain waste. Container was open and information on label was unreadable. Purple staining in sink area

12. Used universal waste lamps in cardboard boxes – not fully closed and not labelled as "universal waste – lamps"

13. Universal waste batteries in container in environmental office

14. 3-gallon "black bin" poly container for bulk or pourable RCRA waste in vials. Chemical waste disposal record sheet showing actual contents of container attached to back of container

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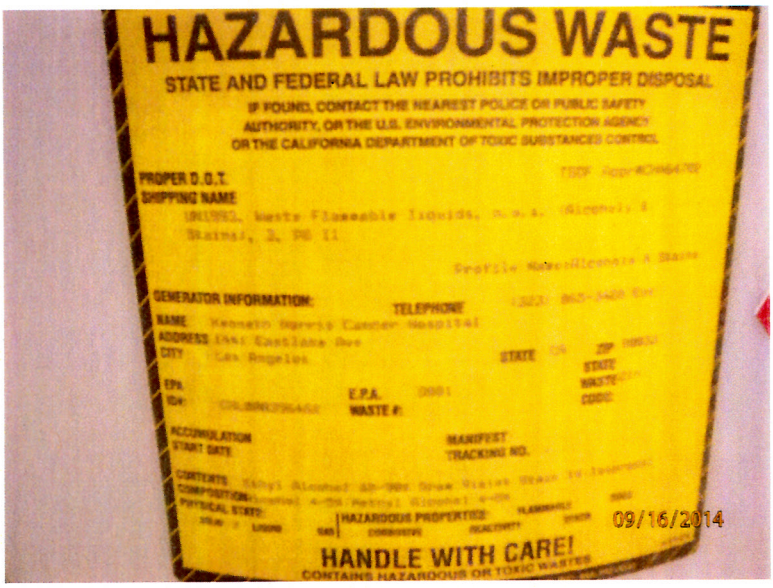

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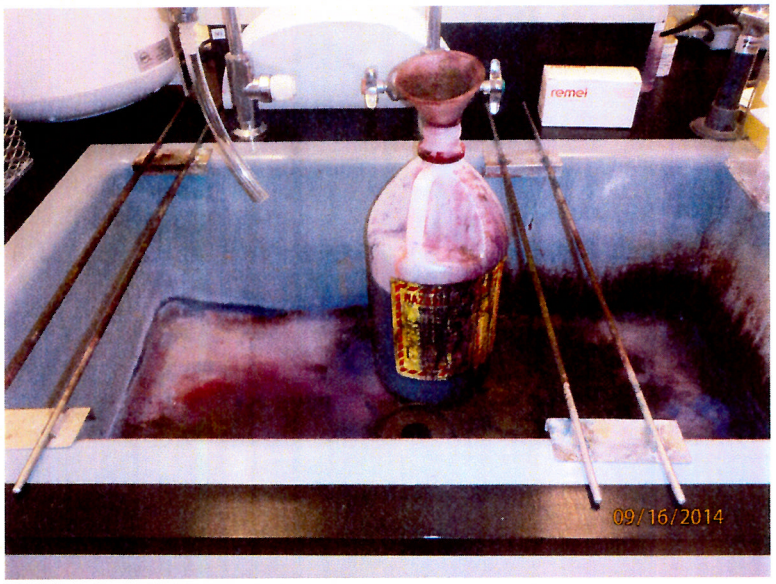

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Attachment 1 - USC Norris Cancer Hospital Inspection Photos

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Attachment 2

USC Norris Cancer Hospital
Chemical Waste Disposal Record, Hazard Class II
Date: 8-17-14

Inpatient Pharmacy (Rm 3341; (323) 865-3601)
For Pick-Up, call (818) 887-1807

	Chemical Name	Concentration(s)	Residual Milligrams/Volumes
1	Arsenic trioxide	1 mg/ml	7ml, 5ml
2	Azacitadine	10 mg/ml, 25 mg/ml	2l
3	Bendamustine	5 mg/ml	
4	Bleomycin	3 units/ml	
5	Bortezomib	1 mg/ml, 2.5 mg/ml	
6	Busulfan	6 mg/ml	1ml, 2ml, 2ml, 0.8ml 2l 2l
7	Carboplatin	10 mg/ml	15ml, 10ml
8	Carmustine	33.3 mg/ml	
9	Cisplatin	1 mg/ml	35l
10	Clofarabine	1 mg/ml	
11	Cytarabine	20 mg/ml, 100 mg/ml	40ml, 40ml, 30ml, 40l, 45l, 4ml, 5l
12	Cyclophosphamide	20 mg/ml	
13	Daunorubicin	5 mg/ml	
14	Decitabine	5 mg/ml	
15	Docetaxel	20 mg/ml	20
16	Doxorubicin	2 mg/ml	18ml, 8ml, 50ml, 10ml
17	Dacarbazine	10 mg/ml	
18	Etoposide	2 mg/ml	
19	Fludarabine	10 mg/ml	
20	Fluorouracil	50 mg/ml	9ml,
21	Ganciclovir	50 mg/ml	3l, 3l, 8ml, 4ml, [illegible], 5ml, 5ml
22	Gemcitabine	38 mg/ml	10ml, 1ml, 2ml
23	Idarubicin	1 mg/ml	
24	Ifosfamide	50 mg/ml	15ml, 5ml, 15ml, 18ml, 15ml, 2ml,
25	Melphalan	5 mg/ml	
26	Methotrexate	25 mg/ml	48ml, 48ml, 30ml, 1ml, 1ml,
27	Mitomycin	0.5 mg/ml, 2 mg/ml	
28	Mitoxantrone	2 mg/ml	
29	Mycophenolate	6 mg/ml	
30	Paclitaxel	6 mg/ml	30ml, 2ml, 2ml,
31	Pegaspargase	750 units/ml	
32	Tacrolimus	5 mg/ml	1.7mg in NS 250ml, 22 mg,
33	Vinblastine	1 mg/ml	10 ml
34	Vincristine	1 mg/ml	1.5l, 1.5l
35	Vinorelbine	10 mg/ml	
36			
37			
38			
39	CYTARABINE	20mg/ml	30ml, 8ml, 4ml,
40	Oxaplatin		4ml,

Norris Cancer Hospital

☒ Ambulatory Pharmacy, Rm# 1355 (323) 865-3614

☐ Inpatient Pharmacy, Rm# 3341 (323) 865-3604

nical Waste Disposal Record, Hazard Class II

Pick-Up Call (818) 887-1807 Date: [illegible]

	Chemical (Carcinogen) Name	Concentration	Residual Milligrams / Volumes
1.	Ara-C	50mg/ml	
2.	Arsenic	1mg/ml	
3.	Bevacizumab	25mg/ml	
4.	Bleomycin	3U/ml, 5U/ml	
5.	Bortezomib (Velcade)	1mg/ml	
6.	Carboplatin	10mg/ml	45ml [illegible]
7.	Cetuximab	2mg/ml	
8.	Cisplatin	1mg/ml	
9.	Cyclophosphamide	20mg/ml	
10.	Docetaxel	10mg/ml	37l 37l [illegible]
11.	Doxorubicin	2mg/ml	
12.	Doxorubicin, Liposomal	2mg/ml	

13.	DTIC	10mg/ml	
14.	Etoposide	20mg/ml	
15.	Fludarabine	25mg/ml	
16.	5-FU	50mg/ml	5ml [illegible] 25ml
17.	Gemcitabine	40mg/ml	3ml
18.	Ifosfamide	50mg/ml	
19.	Irinotecan	20mg/ml	12ml
20.	Methotrexate	25mg/ml	
21.	Mitomycin	0.5mg/ml	
22.	Mitoxantrone	2mg/ml	
23.	Oxaliplatin	5mg/ml	
24.	Paclitaxel	6mg/ml	[illegible] 20ml, 25ml
25.	Paclitaxel Protein Bound	5mg/ml	
26.	Topotecan	1mg/ml	
27.	Vinblastine	1mg/ml	
28.	Vincristine	1mg/ml	
29.	Vinorelbine	10mg/ml	
30.	Rituximab	10mg/ml	320 [illegible]
31.			[illegible]
32.	[illegible]	[illegible]	2ml
33	[illegible]		[illegible]